Citation:

Lappe JM, Rafferty KA, Davies KM, Lypaczewski G. Girls on a high-calcium diet gain weight at the same rate as girls on a normal diet: a pilot study. J Am Diet Assoc. 2004 Sep;104(9):1361-7. PubMed PMID: 15354150.

PubMed ID: 15354150

Study Design:

randomized controlled trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

The purpose was to determine whether girls who followed calcium-rich diets had different weight gain than girls who consumed their usual calcium intakes.

Inclusion Criteria:

- Healthy 9-year-old girls

Exclusion Criteria:

Children with a history of the following were excluded:

- lactose intolerance
- milk allergy
- corticosteroid or anticonvulsant therapy
- familial hypercholesterolemia
- mental or physical handicaps
- cancer
- rheumatoid arthritis
- asthma
- other significant problem reported by the parent
- girls with usual dietary intake of >1,100 mg of calcium/day
- girls who participated in organized team sports ≥ 3 times per week
- girls with a body mass index (BMI) in the 85th percentile or more for age and gender (which was a BMI ≥ 20)

Description of Study Protocol:

Recruitment - Great Plains Girl Scout Council of Omaha and metropolitan area schools

Design - randomized, control

Blinding used (if applicable)

Intervention (if applicable)

- 1500 mg of dietary calcium daily from foods with naturally and fortified calcium sources but no calcium supplements

Statistical Analysis

- Test-retest reliability of the Tanner index of pubertal status was 0.85 in 30 girls from the study.
- For body composition, the coefficient of variation of measurements was 0.7% for lean mass, 1.2% for fat mass, and 1.1% for percent body fat.
- The SPSS program was used for data analysis.
- To assess baseline values and dietary changes, the researchers used descriptive statistics and *t* tests of paired and independent samples.
- Analysis of covariance modeled the effect of tertile of calcium intake on weight gain while adjusting for baseline weight and nutrient intake averaged over the study as covariates/predictors.
- Mann-Whitney U tested the difference in percentile ranking of BMI.

Data Collection Summary:

Timing of Measurements

- Calcium and dietary intake were assessed using 3-day food records. Both groups completed a record every 3 months and brought them to quarterly visits.
- The treatment group consumed at least 1500 mg of calcium daily during the 4 years of the study. Families with girls in the treatment group were given credit at the grocery store for about $13 to buy the calcium-rich foods.
- In addition to the food records, subjects in the treatment group were asked to keep a daily checklist for calcium intake. The checklists were submitted at quarterly visits.
- The control group consumed a usual diet. These subjects were given a healthful eating brochure from the National Dairy Council and were instructed on overall nutrition.
- Dietary intake, physical activity, height, weight, medical history, and pubertal status were assessed at baseline and every 3 months.
- Body fat, lean mass, and bone density were measured semiannually.
- Analysis was done after all girls completed 2 years of the study.

Dependent Variables

- Weight was measured using a balance scale. A Harpenden stadiometer was used to obtain height.
- Pubertal status was assessed using a modified Tanner Index, which was self-administered. Each girl was allowed privacy to review Tanner's photographs and select the picture of breast development that closely matched her own.
- Body composition was measured with the Hologic 4500 dual energy x-ray absorptiometer.

Independent Variables

- Dietary calcium intake : calcium rich diet (1500 mg/day) versus usual diet

Control Variables

- Usual physical activity was self-reported using a tool from Slemenda and colleagues

Description of Actual Data Sample:

Initial N: 63 girls

Attrition (final N): 59

Age: 9 years

Ethnicity: 2 non-Hispanic black girls, 57 non-Hispanic white girls

Other relevant demographics: not described

Anthropometrics: all were premenarcheal and in Tanner Stage 1 for breast development at the start of the study, and 13 had experienced menarche by the end of the study.

BMI (Mean)

- treatment group at baseline: 17 ± 2.0
- control group at baseline: 17 ± 3.0

Fat mass (Mean)

- treatment group at baseline: 7.9 ± 2.6
- control group at baseline: 8.6 ± 3.2

Lean mass (Mean)

- treatment group at baseline: 24.7 ± 3.2
- control group at baseline: 25.1 ± 3.6

Location: Osteoporosis Research Center, Creighton University, Omaha, Nebraska

Summary of Results:

Key Findings:

- Participants in the treatment group had no significant differences in weight, BMI, or body mass when compared to the control group.
  - *BMI (Mean)*
    - treatment group at 24 months: 19 ± 2.8
    - control group at 24 months: 19 ± 3.3
  - *Fat mass (Mean)*
    - treatment group at 24 months: 10.7 ± 3.6
    - control group at 24 months: 11.4 ± 4.9
  - *Lean mass (Mean)*
    - treatment group at 24 months: 32.6 ± 5.2
    - control group at 24 months: 33.3 ± 6.3

Variables	Treatment group	Control group	Statistical difference
Weight increase (mean)	34% (range 17% - 59%)	33% (range 16% - 72%)	none noted
Lean mass increase (mean)	31% (range 15% - 55%)	31% (range 11% - 54%)	none noted
Fat mass increase (mean)	38% (range 6% - 75%)	0% (range 17% - 139%)	none noted
Height increase (mean)	7%	7%	none noted

Other Findings:

When calcium intake was analyzed as tertiles of intake, the only significant predictor of change in weight was baseline weight (P=0;.0006), and the predictors of change in BMI were baseline BMI (P<0.02), mean energy intake (P<0.01), and mean protein intake (P<0.02).v

Author Conclusion:

A calcium-rich diet does not cause disproportionate increases in body weight.

Reviewer Comments:

pilot study with a small sample size; self-reported intake, although imprecise, was consistent over time

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Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	No
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes
Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes

3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	No
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	N/A
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes

10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes